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**PATENT APPLICATION**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re application of

Docket No: Q86357

Tetsuro KIKUCHI, et al.

Appln. No.: 10/540,577

Group Art Unit: 1614

Confirmation No.: 6428

Examiner: Not Yet Assigned

Filed: June 24, 2005

For: CARBOSTYRIL DERIVATES AND SEROTONIN REUPTAKE INHIBITORS FOR  
TREATMENT OF MOOD DISORDERS

**INFORMATION DISCLOSURE STATEMENT**  
**UNDER 37 C.F.R. §§ 1.97 and 1.98**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

In accordance with the duty of disclosure under 37 C.F.R. § 1.56, Applicants hereby notify the U.S. Patent and Trademark Office of the documents which are listed on the attached PTO/SB/08 A & B (modified) form which the Examiner may deem material to patentability of the claims of the above-identified application.

Additionally, Applicants wish to bring to the Examiner's attention the following two items of information which may be considered relevant to the examination of the present application:

(1) A particular form of the drug aripiprazole known as "Anhydrous Aripiprazole Crystals B" was approved by the Food and Drug Administration on November 15, 2002 and

INFORMATION DISCLOSURE STATEMENT  
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launched into the U.S. market after November 15, 2002 by a U.S. licensee of Otsuka Pharmaceutical Co., Ltd.

(2) WO 03/026659 A1, a PCT international application assigned to Otsuka, discloses a process for preparing Anhydrous Aripiprazole Crystals B and was published April 3, 2003. A copy of WO 03/026659 A1 is submitted with this Information Disclosure Statement.

The present Information Disclosure Statement is being filed: (1) No later than three months from the application's filing date; (2) Before the mailing date of the first Office Action on the merits (whichever is later); or (3) Before the mailing date of the first Office Action after filing a request for continued examination (RCE) under §1.114, and therefore, no Statement under 37 C.F.R. § 1.97(e) or fee under 37 C.F.R. § 1.17(p) is required.

The attached Form PTO/SB/08 includes the four documents listed on the Search Report dated June 15, 2006 for the corresponding Georgian application. The non-U.S. patent documents have not yet been received from the Georgian associate. When received, they will be submitted to complete the record. In compliance with the concise explanation requirement under 37 C.F.R. § 1.98(a)(3) for foreign language documents, Applicants enclose herewith a copy of the Search Report from the Georgian patent office in the counterpart Georgian application citing such documents, together with an English-language version of the report indicating the degree of relevance found by the foreign patent office.

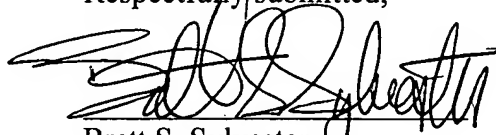
The submission of the listed documents is not intended as an admission that any such document constitutes prior art against the claims of the present application. Applicants do not

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waive any right to take any action that would be appropriate to antedate or otherwise remove any listed document as a competent reference against the claims of the present application.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Brett S. Sylvester", written over a horizontal line.

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WASHINGTON OFFICE

**23373**

CUSTOMER NUMBER

Date: November 3, 2006



Substitute for Form 1449 A &amp; B/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

**Complete if Known**

Application Number	10/540,577
Confirmation Number	6428
Filing Date	June 24, 2005
First Named Inventor	Tetsuro KIKUCHI
Art Unit	1614
Examiner Name	
Attorney Docket Number	Q86357

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**U.S. PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Document Number		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document
		Number	Kind Code <sup>2</sup> (if known)		
		US 60/319,436			Peter Migaly
		US 2004/0204401	A1	10-14-2004	Peter Migaly
		US 2002/0156067	A1	10-24-2002	Wong et al
		US			
		US			
		US			
		US			
		US			
		US			
		US			
		US			

**FOREIGN PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document			Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Translation <sup>6</sup>
		Country Code <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)			
		WO	03026659		04-03-2003	Otsuka Pharmaceutical Co., Ltd.	
		RU	2181287	C	04-20-2002		
		RU	94037967	A1	08-27-1996		

**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city, and/or country where published.	Translation <sup>6</sup>
		Lawler C. P. et al, "Interaction of the Novel Antipsychotic Aripiprazole (OPC-14597) with Dopamine and Serotonin Receptor Subtypes," Neuropsychopharmacology, 1999, Vol. 20, No. 6. pp. 612-627	
		Copy of Georgian Search Report dated June 15, 2006	

Examiner Signature		Date Considered	
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kind Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov), MPEP 901.04 or follow the hyperlink from the title of the document to the intranet. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST. 3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to indicate here if English language Translation is attached.